



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Smith, RL et al Application No.: 10/616,047 Filed: 7-7-2003
Group Art Unit: 1616 Docket No. 0723 Examiner: J. Pak

Title: Stable Hydrogen Peroxide Compositions, Products and Methods of Use

Date: May 16, 2005

To: Mail Stop Non-fee Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

AMENDMENT

In response to the Office Action dated March 1, 2005 please amend the above-identified patent application, without prejudice, as follows:

A. AMENDMENTS TO THE CLAIMS

Please cancel claims 4, 9-23 and 25-27 as originally filed and amend claims 1-8 and 24 and add new claims 28, 29, and 30.

Claim 1 (currently amended)

1. An aqueous solution of H_2O_2 (hydrogen peroxide) that is dispensed [by a consumer] for topical use as a stable foam for the treatment of minor skin injuries comprising

- a) a 0.1% to 15% solution of H_2O_2 ;
- b) about 1% of a surfactant;
- c) [less than] from about 0.05% to 1% of a stabilizer;
- d) at least one non-ingestable skin protectant; and
- e) at least one topical pain reliever

that is packaged in a container equipped with a pump foaming chamber that produces foam without the use of gas propellants and delivers H_2O_2 topically to a wound by finger-depression of a foam dispenser.

Claim 2 (currently amended)

2. The **peroxide** foam of claim 1 wherein the surfactant is a non-ionic surfactant selected from the group consisting of octoxynol 9, laneth-4, steareth-4, oleth-4, ceteth-10, laneth-10, steareth-10, oleth-10, ceteth-20, polysorbates 20 and 80, and combinations thereof.

Claim 3 (currently amended)

3. The **peroxide** foam of claim 1 wherein the stabilizer is sodium pyrophosphate.

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Claim 4 is cancelled

Claim 5 (currently amended)

- 15 5. The **peroxide** foam of claim [4] **1** wherein the topical pain relievers are selected from the group consisting of benzocaine, butamben picrate, dibucaine hydrochloride, dimethisoquin hydrochloride, dyclonine hydrochloride, lidocaine, lidocaine hydrochloride, pramoxine hydrochloride, tetracaine, tetracaine hydrochloride, benzyl alcohol, camphor, camphorated metacresol, juniper, [menthol], phenol, phenolate sodium, resorcinol, diphenhydramine hydrochloride, tripelenamine hydrochloride, hydrocortisone, hydrocortisone acetate, methyl salicylate, [menthol], methyl nicotinate, capsaicin, capsaicin oleoresin and combinations thereof.

25 Claim 6 (currently amended)

6. The **peroxide** foam of claim [4] **1** wherein the **non-ingestible topical** skin protectants are selected from the group consisting of [glycerin, propylene glycol, allantoin,] aluminum hydroxide gel, calamine, [cocoa butter,] kaolin, petrolatum, dimethicone, [shark liver oil, zinc acetate, zinc carbonate, sodium bicarbonate, cod liver oil, mineral oil, colloidal oatmeal, and zinc oxide.], talc, lanolin, **and** topical starch.

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Claim 7 is cancelled

Claim 8 (original)

- 5 8. The foam of claim 1 wherein the H₂O₂ foam dispensing device comprises a reversibly compressible and decompressible container housing which operates at atmospheric pressure.

Claim 9 (canceled)

Claim 10 (canceled)

- 10 Claim 11 (canceled)

Claim 12 (canceled)

Claim 13 (canceled)

Claim 14 (canceled)

Claim 15 (canceled)

- 15 Claim 16 (canceled)

Claim 17 (canceled)

Claim 18 (canceled)

Claim 19 (canceled)

Claim 20 (canceled)

- 20 Claim 21 (canceled)

Claim 22 (canceled)

Claim 23 (canceled)

Claim 24 (currently amended)

- 25 24. A method for treating topical wounds **of the skin** with a composition of hydrogen peroxide (H₂O₂) which comprises applying a foam composition comprising from 0.1 to 15% hydrogen peroxide, stabilized with minor amounts of sodium pyrophosphate **and formulated with a surfactant, at least one non-ingestible skin protectant, and at least one**
- 30 **topical pain reliever** to [the] a wound site by depressing a finger-activated pump foaming device in the immediate vicinity of

said wound

allowing the peroxide to come into contact with the wound without the need for additional application means and

allowing the peroxide to treat the wound **without dripping off the skin surface**

5 **to which it was applied.**

Claim 25 (canceled)

Claim 26 (canceled)

Claim 27 (canceled)

10 Claim 28 (new)

28. The method of claim 24 wherein the topical pain reliever is selected from the group consisting of benzocaine, butamben picrate, dibucaine hydrochloride, dimethisoquin hydrochloride, dyclonine hydrochloride, lidocaine, lidocaine hydrochloride, pramoxine hydrochloride, tetracaine, tetracaine hydrochloride,
15 benzyl alcohol, camphor, camphorated metacresol, juniper, phenol, phenolate sodium, resorcinol, diphenhydramine hydrochloride, tripelenamine hydrochloride, hydrocortisone, hydrocortisone acetate, methyl salicylate, methyl nicotinate, capsaicin, capsaicin oleoresin and combinations thereof.

20 Claim 29 (new)

29. The method of claim 24 wherein the non-ingestible topical sin protectants are selected from the group consisting of aluminum hydroxide gel, calamine, kaolin, petrolatum, dimethicone, talc, lanolin, and topical starch.

25 Claim 30 (new)

30. The peroxide foam of claim 1 wherein the shelf life is about two years.